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APR 1 2 2013

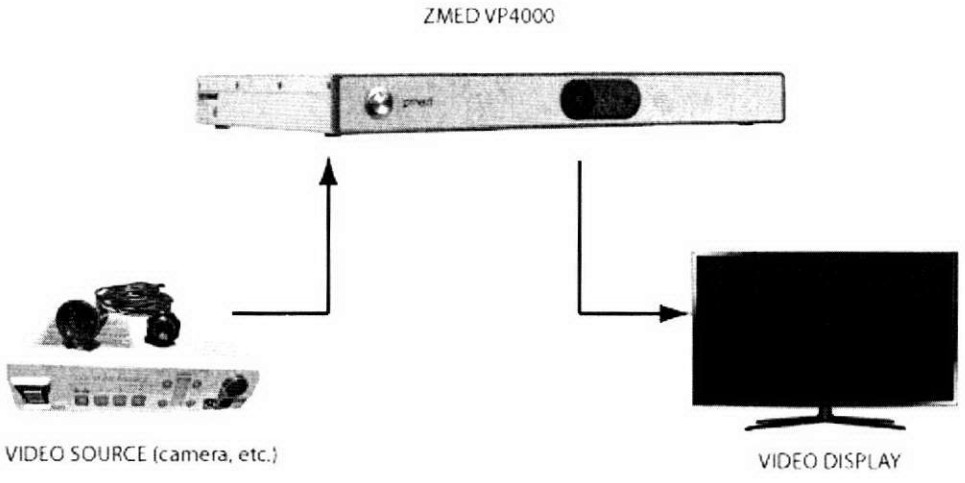
APPENDIX 1 510(k) SUMMARY

APPLICANT:	ZMED, Inc. 9820 Summers Ridge Road San Diego, CA 92121 858.831.7000
CONTACT:	Randall S. Millar 858.831.7059
DATE OF SUMMARY:	20 MARCH 2013
DEVICE NAME:	ZMED VP4000 Video Processor
PREDICATE DEVICE:	DigiVision CE3000 FDA 510(k) file #: K962260 Year approved: 1996

DEVICE DESCRIPTION

The ZMED VP4000 is a simple-to install, easy to use video processing system which provides powerful real-time enhancement of input video signals. The enhanced output video provides increased clarity, contrast, and detail, aiding in the ability to see through smoke, in poor lighting conditions, and other sub-optimal conditions.

The VP4000 is connected between a video source and a display. An example of a typical installation is shown below:



The system uses standard electronic components to implement patented algorithms which are designed to improve the ability of the human eye to perceive fine details in the image which might otherwise be obscured by smoke, haze, poor lighting, etc. This is accomplished via a combination of locally-adaptive contrast enhancement using a very large-kernel convolution operation (identical to that used in the CE3000), and histogram-based operations. Like the CE3000, a key feature of the VP4000 is its ability to perform these complex operations in real time, adding virtually imperceptible system latency from input of raw video to output of enhanced video. The effectiveness of the algorithms combined with this real-time capability makes the VP4000 ideally suited for use in applications which live video is required to perform a given function.

The VP4000 chassis is constructed of lightweight aluminum, measures 15.7" wide by 12.0" deep by 1.7" high, and weighs 4.95 pounds. The device is compatible with DVI-D and HD-SDI video signals in a variety of standard resolutions, up to 1080p. Internally, the VP4000 is constructed using UL- and IEC-approved components, circuit boards, and harnessing. The VP4000 has been successfully tested to meet IEC60601-1 Second Edition safety standards, and FCC Part 15 Subpart B. These tests were performed by:

TÜV SÜD America Inc.,
10040 Mesa Rim Road, San Diego, CA 92121
Tel: (858) 678-1400

No adaptations to or deviations from these Standards were employed during testing.

STATEMENT OF INTENDED USE

" The ZMED VP4000 Video Processor is intended for use in any application where a viewing device (fluoroscope, endoscope, laparoscope, etc.) and monitor are incorporated to aid in diagnosis and treatment of a disease such as an arthroscopy or cholecystectomy."

This statement is virtually identical to that of the predicate device (CE3000). Both the subject and predicate devices have the same function and purpose and the differences in intended use do not create new safety or effectiveness issues.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The VP4000 is an evolutionary development of the CE3000. Whereas the CE3000 is compatible with outdated analog video signals, the VP4000 has been designed to work with modern high-definition digital video formats. Additionally, advancements in electronic component capability since the CE3000 was designed have allowed for a higher degree of integration (fewer components required) when implementing the enhancement algorithms.

Both systems operate on standard AC power (100-240VAC). Both systems utilize an internal medical-grade power supply to convert the input AC power to low-voltage DC supplies for use by the electronics. Refer to the table below for a

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summary comparison of changes between the unmodified (CE3000) and proposed (VP4000) devices.

Features	VP4000	CE3000 (unmodified)
Similarities		
Intended Use	The ZMED VP4000 Video Processor is intended for use in any application where a viewing device (fluoroscope, endoscope, laparoscope, etc.) and monitor are incorporated to aid in diagnosis and treatment of a disease such as an arthroscopy or cholecystectomy.	The CE3000 Contrast Enhancer like the FluoroVision, may be used in any application where a viewing device (fluoroscope, endoscope, laparoscope, etc.) and monitor is incorporated to aid in diagnosis and treatment of a disease such as an arthroscopy or cholecystectomy.
Device	Non-patient contact	Non-patient contact
Category	Pre-market notification 510(k)	Approved via 510(k) submission
Technology	Real-time video enhancement	Real-time video enhancement
Differences		
User Interface	Simplified, selectable presets	Individual controls for parametric settings
Supported video formats	Digital, high-definition	Analog, standard-definition

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 12, 2013

ZMed, Inc.
% Mr. Randall Millar
VP of Engineering
9820 Summers Ridge Road
SAN DIEGO CA 92121

Re: K130929
Trade/Device Name: ZMED VP4000 Video Processor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 27, 2013
Received: April 3, 2013

Dear Mr. Millar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130929

Device Name: ZMED VP4000 Video Processor

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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